In vitro diagnostic medical devices: security requirements

1995/0013(COD) - 18/06/1998 - Text adopted by Parliament, 2nd reading

In adopting the recommendation for second reading by Mr Alain POMPIDOU (UPEF) European Parliament stressed the need. - to draw up as quickly as possible legislation concerning medical devices manufactured from substance of human origin; - avoid distortion of competition concerning self testing devices; - translate into the language of the final user the instructions for use and the labelling of self test devices; - include screening methods by serum tests of chromosome 21; - development market DNA microchips with a view to screening for genetic diseases or the predisposition to certain genetic diseases (concerning which manufacture should inform the relevant authorities of the introduction of new products onto the market with regard to both the technology used and the substances to be analysed or other parameters; - preserve the confidentiality of information concerning persons undergoing diagnosis or tests and protect individuals against any discrimination based on inherited genetic characteristic of men and women.